UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

RAHSAN A. HAKIM and
ADONIIAH A. RAHSAN,
d/b/a SUNDIAL HERBAL PRODUCTS,

Defendants.

18 Civ. 5726 (ER)

~~[PROPOSED]~~ ORDER OF PERMANENT INJUNCTION

WHEREAS, on June 25, 2018, Plaintiff, the United States of America (the "United States"), on behalf of the United States Food and Drug Administration ("FDA"), filed a Complaint for Permanent Injunction (the "Complaint") against Rahsan A. Hakim (also known as Rudolph I. Duckett, Rashan Duckett, and Rahsam Ahkin) and Adoniiah A. Rahsan (also known as Adoni-iah Hakim), individuals (collectively, "Defendants"), doing business as Sundial Herbal Products, an unincorporated entity that Defendants have identified as a partnership, alleging that Defendants have violated, and threaten to violate in the future, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA" or "the Act"), and its applicable regulations;

WHEREAS this Court finds that Defendants have violated, and threaten to violate in the future, the FDCA and its applicable regulations;

NOW, THEREFORE, it is hereby ORDERED as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

2. Venue is appropriate pursuant to 28 U.S.C. § 1391, because Defendants conduct business in this district.

FINDINGS OF FACT

3. This Court finds that:

A. Defendants manufacture, package, label, and distribute numerous tonics, herbs, and herbal teas through their company Sundial Herbal Products ("Sundial"), predominantly at and from their manufacturing facility at 3609 Boston Road, Bronx, New York 10466 (the "Facility"). Sundial's products are also sold at: the Koromantee Health Food Store, which is in the same building as the Facility and is co-owned by Hakim and Rahsan; and on Sundial's website, www.sundialherbs.com. [Plaintiff's Statement of Material Facts Pursuant to Local Civil Rule 56.1 ("Pl. 56.1"), ¶¶ 1, 4-13]

B. Hakim is Sundial's co-owner. He shares responsibility for overseeing the company with his son, Rahsan. Hakim has formulated proprietary blends for the products manufactured by Sundial. Hakim is responsible for Sundial's manufacturing operations and major financial decisions. [Pl. 56.1, ¶ 2]

C. Rahsan is Sundial's co-owner. He oversees Sundial with his father, Hakim, and is responsible for quality control and sales. [Pl. 56.1, ¶ 3]

D. Defendants receive components that they use in the manufacturing of their finished products from outside New York State, including from Jamaica. As such, Defendants' products are manufactured using components that are shipped in interstate commerce under 21

U.S.C. § 331(k). Defendants also ship their finished products in interstate commerce, as that term is defined in 21 U.S.C. § 321(b)(1), from New York to North Carolina. Such shipments constitute the introduction or delivery for introduction into interstate commerce within the meaning of 21 U.S.C. § 331(a) and (d). [Pl. 56.1, ¶¶ 25-28]

E. In 2012, FDA conducted an inspection of the Facility, and issued a Warning Letter dated May 24, 2013, informing Defendants that certain of their products were unapproved new drugs and misbranded drugs. [Pl. 56.1, ¶¶ 14-18]

F. In 2014, FDA conducted another inspection of the Facility, and recorded that certain of Defendants' products were unapproved new drugs and misbranded drugs. [Pl. 56.1, ¶ 19]

G. In 2017, FDA conducted another inspection of the Facility, during which an FDA investigator informed Defendants that certain of their products were unapproved new drugs and misbranded drugs, as previously discussed in the May 24, 2013, Warning Letter. [Pl. 56.1, ¶¶ 21, 24, 29, 30]

H. Certain products manufactured and sold by Defendants are articles of drugs, as defined in 21 U.S.C. § 321(g), and that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labels fails to bear adequate directions for use. [Pl. 56.1, ¶¶ 32-37]

I. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i). [Pl. 56.1, ¶¶ 27, 32-36, 38, 39]

J. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1). [Pl. 56.1, ¶¶ 25-28, 32-39]

K. Defendants violate 21 U.S.C. § 331(k) by causing articles of drugs that Defendants hold for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1). [Pl. 56.1, ¶¶ 25-28]

L. Defendants have repeatedly manufactured and sold unapproved new drugs and misbranded drugs, and caused drugs to become misbranded after shipment of one of more of their components in interstate commerce. [Pl. 56. 1, ¶¶ 24-28, 32-38]

INJUNCTIVE RELIEF

4. Upon entry of this Order of Permanent Injunction ("Order"), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise are **permanently restrained and enjoined** under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any drug at or from the Facility, or at or from any other location(s) at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, pack, label, hold, and/or distribute any drug, unless and until:

A. For all of Defendants' drugs, either:

1. an approved new drug application, an abbreviated new drug application, or an effective investigational new drug application is filed pursuant to 21 U.S.C. § 355(b), (j), or is in effect for such drugs; or

2. the following requirements are met:

(a) Defendants remove from product labels; labeling; promotional material; websites or social media pages owned, controlled by, or related to Defendants including, but not limited to, www.sundialherbs.com, and any future website(s) or social media pages created, controlled by, or related to Defendants; and any other media over which Defendants have control: (i) all representations that the products diagnose, cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a drug within the meaning of the Act; and (ii) all references, direct or indirect, to other sources that contain representations that Defendants' products diagnose, cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of Defendants' products to be a drug within the meaning of the Act;

(b) Defendants retain, at their expense, an independent person or persons (the "Drug Labeling Expert") to review the representations Defendants make for each of their products on product labels; labeling; promotional material; websites or social media pages owned, controlled by, or related to Defendants including, but not limited to, www.sundialherbs.com, and any future website(s) or social media page(s) created, controlled by, or related to Defendants; and any other media over which Defendants have control. The Drug Labeling Expert shall submit a report certifying in writing to FDA that: (i) he or she has inspected the Facility, and any other locations at which Defendants now, or in the future, directly or indirectly receive, prepare, process, manufacture, pack, label, hold, and/or distribute drugs; (ii) he or she has identified all of Defendants' products and reviewed Defendants' representations for each product on product labels; labeling; promotional material; websites or social media pages owned, controlled by, or related to Defendants (including, but not limited to

www.sundialherbs.com); any future website(s) or social medial page(s) created, controlled by, or related to Defendants; and any other media over which Defendants have control; (iii) Defendants have removed all representations that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g); and (iv) based upon the Drug Labeling Expert's inspection and review, Defendants are operating in conformity with the Act, its implementing regulations, and this Order. The Drug Labeling Expert's written certification shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed. The Drug Labeling Expert shall be qualified by education, training, and experience to conduct such inspections and review, and shall be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Drug Labeling Expert within ten (10) business days of retaining such Drug Labeling Expert;

B. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in Paragraph 5, all drugs manufactured, processed, packed, labeled, held, and/or distributed during the time period beginning January 1, 2014, through and including the date of entry of this Order. Defendants shall bear the costs of destruction and the costs of FDA's supervision;

C. Should the Drug Labeling Expert identify any deficiencies in his or her report as described in Paragraph 4.A.2(b):

1. Defendants shall report to FDA and the Drug Labeling Expert in writing the actions they have taken to correct such deficiencies; and

2. The Drug Labeling Expert shall certify in writing to FDA, based upon the Drug Labeling Expert's further review and/or inspections(s), whether Defendants have

removed all claims from each of their product labels, labeling, websites or social media pages owned or controlled by Defendants, and in any other media that cause any of Defendants' products to be drugs within the meaning of the Act;

D. FDA representatives inspect the Facility to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with this Order, the Act, and its implementing regulations;

E. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 4, at the rates set forth in Paragraph 12; and

F. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 4.A through C, and Paragraph 4.E of this Order. In no circumstance shall FDA's silence be construed as a substitute for written notification.

5. Within fifteen (15) business days after the entry of this Order, Defendants shall give notice to FDA that, under FDA's supervision, Defendants are prepared to destroy all drugs (including components and raw and in-process materials and finished products) in Defendants' possession, custody, or control. Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. Within fifteen (15) business days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision, complete the destruction in compliance with this Order. Defendants shall not dispose of any such products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any state or

Territory, as defined in the Act, in which the products are disposed. Defendants shall bear the costs of destruction and FDA's supervision.

6. Upon resuming operations after complying with the requirements of Paragraph 4 and receiving FDA's written notification pursuant to Paragraph 4.F, Defendants shall retain an independent person or persons who shall meet the criteria for, and may be the same person as, the Drug Labeling Expert described in Paragraph 4.A.2(b) (hereinafter, the "Auditor") to conduct audit inspections of the Facility no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 4.F.

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Order, the Act, and its implementing regulations, and identifying any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (a) has personally reviewed all of Defendants' product labels, labeling, and websites or social media pages; and (b) personally certifies whether or not the product labels, labeling, and websites or social media pages make claims that cause Defendants' products to be drugs within the meaning of the Act.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the Audit Report

is completed. In addition, Defendants shall maintain the Audit Reports in separate files at the Facility and shall promptly make the Audit Reports available to FDA upon request; and

D. If an Audit Report contains any observations indicating that Defendants' products are not in compliance with this Order, the Act, or its implementing regulations, Defendants shall, within fifteen (15) business days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than fifteen (15) business days, Defendants shall, within ten (10) business days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within twenty (20) business days of the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days of beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

7. Upon entry of this Order, Defendants, and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities

in active concert or participation with any of them, are **permanently restrained and enjoined** under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered for introduction, into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. Violating 21 U.S.C. § 331(k), by causing drugs, as defined in 21 U.S.C. § 321(g), that Defendants hold for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

D. Failing to implement and continuously maintain the requirements of the Act, its implementing regulations, and this Order.

8. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, or websites or social media pages owned or controlled by Defendants, a report prepared by Defendants' Drug Labeling Expert or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with the Act, its implementing regulations, and/or this Order, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective

action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug that is adulterated, misbranded, or otherwise in violation of this Order, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Order, the Act, or its implementing regulations. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Order or under the law.

9. Upon receipt of any order issued by FDA pursuant to Paragraph 8, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 8 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph 12.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any

other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, manufacture, preparing, processing, packing, repacking, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Within ten (10) business days after FDA's request for Defendants' labels, labeling, promotional materials, websites or social media pages, and any other media over which Defendants have control containing representations about the intended use(s) of Defendants' products, Defendants shall submit a copy of the requested materials (in hard copy or, if appropriate, on CD-ROM) to FDA at the address specified in Paragraph 17.

12. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Order at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Order, these rates are: $97.57 per hour or fraction thereof per representative for inspection and investigative work; $132.89 per hour or fraction thereof per representative for analytical or review work; $0.58 per mile for travel

expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. Within five (5) business days after the entry of this Order, Defendants shall post a copy of this Order in a common area at the Facility and at any other location at which Defendants conduct business, and shall ensure that the Order remains posted for as long as the Order remains in effect. Within ten (10) business days after entry of this Order, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

14. Within ten (10) business days after the entry of this Order, Defendants shall provide a copy of the Order by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them ("Associated Persons"), including, but not limited to: Koromantee Health Food Store, located at 3609 Boston Road, Bronx, NY 10466; Sundial Herbs and Herbal Health Food Shoppe, located at 538 Jerusalem Avenue, Uniondale, NJ 11553; Sundial Herb and Herbal Products, Inc. Ltd., located in Kingston, Jamaica; Sundial Herbs & Herbal Products Enterprises, Inc., located at 3609 Boston Road, Bronx, NY 10466; and Sundial Herbs & Herbal Products, LLC, located at 739 Nereid Ave., Bronx, NY 10466. Within twenty (20) business days after the date of entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Order.

15. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants shall within ten (10) business days after the commencement of such association: (a) provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s); and (b) provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Order pursuant to this paragraph.

16. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Sundial Herbal Products, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

17. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be addressed to: Director, Office of Human and Animal Food Operations-East, Division of Human and Animal Food Operations East I, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433.

18. Should Defendants fail to comply with any provision of this Order, the Act, or its implementing regulations, including any time frame imposed by this Order, then Defendants

shall pay to the United States of America: Five Thousand Dollars ($5,000.00) in liquidated damages for each day such violation continues; an additional sum of Three Thousand Dollars ($3,000.00) in liquidated damages per day, per violation for each violation of this Order, the Act, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed drugs that are unapproved or misbranded or otherwise in violation of this Order, the Act, or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Order, any other order to which Defendants are subject, or the law.

19. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

20. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

21. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 27 day of May, 2020.

UNITED STATES DISTRICT JUDGE